



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Health and Environmental Effects Research Laboratory
Environmental Public Health Division
Research Triangle Park, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

March 21, 2016

MEMORANDUM

SUBJECT: Technical Systems Audit of the project "An epidemiologic health study of manganese (Mn) exposure in East Liverpool, Ohio"

FROM: Mike Ray
EPHD QA Manager, MD-58A

TO: Dr. Danelle Lobdell, Project Officer for NHEERL
EPHD, MD-58A

This memo is to advise you that your RARE grant project "An epidemiologic health study of manganese (Mn) exposure in East Liverpool, Ohio" has been identified as one of the elements of the overall research program of the National Health and Environmental Effects Research Laboratory (NHEERL) that will undergo a quality assurance (QA) audit. The audit, a Technical Systems Audit (TSA), will be performed by EPHD's Quality Assurance Manager.

The purposes of the review are to determine

1. whether research planning is appropriate to assure that the quality of the research and resulting data are adequately addressed,
2. whether the research is being performed as planned, as well as whether documentation exists to confirm that such is the case, and
3. whether the quality or uncertainty of the data is reported to those who may use it.

Both exemplary and problematic observations will be shared with you and Drs. Tim Wade and Wayne Cascio. You will be provided a draft final audit report for your comments which will be reconciled in the final report; a period of 30 days is allowed for your response after issuance of the draft report. Subsequent to your response, copies of the final report will be released and provided to the people mentioned above. Again, the primary objective of the TSA is to assist scientists, whenever possible, in adequately addressing quality-related issues in planning and conducting research to support EPA, and to create accurate and defensible records of research data.

The on-site review will be performed on November 5-6, 2011 by Mike Ray, EPHD QA Manager.

In preparation for this review, the following information has been obtained:

IRB Proposal entitled *An epidemiologic health study of manganese (Mn) exposure in East Liverpool, Ohio*, including the neurophysiological test battery descriptions (8/4/11)

Request for Professional Services: Dr. Rosemarie Bowler, San Francisco State University

During my visit to your field site, I would like to have available for review the documentation listed on page 4 of this memo. If records are maintained outside your field site, I should like to obtain copies of the information applicable to this study or have access to same. I will attempt to cause as little disruption as possible in your performance of daily routine activities.

Please find attached a copy of the checklist, containing my preliminary notes to be used as a guide to conduct the TSA. To expedite the TSA process, please respond to as many checklist items as you deem appropriate prior to my visit.

My proposed agenda for the TSA is shown below.

November 5 (Saturday) – East Liverpool, OH

- (1) Introductory meeting with the San Francisco State University Principal Investigator and key staff
- (2) Tour of the field site
- (3) Observation of field staff administering consent forms and questionnaires
- (4) Observation of field staff administering neurophysiological tests and processing blood, serum, hair, and toenail samples
- (5) Interviews with the Principal Investigator and key staff to review procedures and records at the field site and to complete the TSA checklist

November 6 (Sunday) – East Liverpool, OH

- (1) Interviews with the Principal Investigator and key staff to review procedures and records at the field site and to complete the TSA checklist
- (2) Exit meeting with the San Francisco State University Principal Investigator and key staff

I anticipate that the introductory and exit meetings and the site tour should each take less than one hour. It is difficult to estimate the time duration of the other events because it will depend on the individuals' responsibilities and the nature and condition of the documentation to be reviewed. If you have any questions, concerns, or recommendations regarding the proposed agenda, please contact Mike Ray (telephone: 919-966-0625; fax: 919-966-6212; E-mail: ray.mike@epamail.epa.gov).

I greatly appreciate your cooperation in this effort.

Attachment
cc

T. Wade
W. Cascio

**RECORDS REQUESTED TO BE AVAILABLE FOR REVIEW
DURING THE TECHNICAL SYSTEMS AUDIT (if not previously provided)**
**NHEERL Project Title: “An epidemiologic health study of manganese (Mn) exposure in East Liverpool,
Ohio”**

- (1) QA plans that were not previously submitted or that have since been modified
- (2) Written operating procedures (OPs)
 - ! OPs that were not previously submitted or that have since been modified
 - ! Published methods or operating manuals that are followed when OPs are not used
 - ! Records pertaining to the validation of ROPs/SOPs
- (3) Laboratory notebooks and standard data forms (in which original documentation of experimental procedures, observations, and results is maintained) and records of untoward events not covered in routine documentation (incident reports, unscheduled experiments, repairs, etc.)
- (4) Records on human study subjects
 - ! Completed questionnaires
 - ! Completed neurophysiological tests
 - ! Blood, serum, hair, and toenail samples
- (5) Peer review correspondence
- (6) Instrument printouts or other outputs
- (7) Instrument and equipment quality control, maintenance, and calibration records
- (8) Data backup